REMARKS

Claim Rejections – 35 USC § 103 - Claims 1, 15 to 21 and 34 to 38

The Examiner rejected claims 1, 15 to 21 and 34 to 38 of the application as being unpatentable over Hed (US Patent 5,301,090) in view of Reichborn-Kjennerud *et al.* (1996) Response to Light Therapy in Seasonal Affective Disorder: personality disorders and temperament as predictors of outcome. J Affect Disord 41:101-110.

In summary, the Examiner has alleged that the invention as defined by these claims is obvious because Hed teaches a light therapy device including LEDs and Reichborn-Kjennerud *et al.* disclose light therapy for SAD using light levels of about 1500 lux at eye level.

As submitted in applicants' response filed May 29, 2008, these references alone or in combination do not render the claims obvious.

Applicants previously submitted and repeat here:

- Hed neither teaches nor suggests a light treatment device with LEDs as the light source or any method for using same.
- The only light treatment device taught by Hed uses remote high intensity discharge (HID) light sources and light extraction including conductive cables to transmit light from the HID lights to a light therapy delivery location.
- Hed teaches away from the use of LEDs in a light therapy device and, therefore, teaches away from the present invention.

In response to the applicants' extensive arguments supporting and explaining the above-noted facts, the Examiner incorrectly states at page 3 that "Hed having disclosed resetting the circadian clock as the intended use of the luminaire, no limitation regarding the various embodiments can be inferred". Applicant cannot agree. On the contrary, Hed clearly teaches that limitations regarding the various embodiments should be

inferred and only discloses resetting the circadian clock as the intended use of some of his luminaires, not all of them. Consider the following:

Hed, Column 2, lines 33 to 41:

> "*It is also an object of the invention to provide a luminaire particularly suitable for the modification and resetting of human circadian cycle, as taught by C. A. Czeisler in U.S. patent application Ser. No. 07/066,677, where very high intensity light sources capable of delivering at least 7500 lux are required, and, when desired, without having to discharge the heat generated from such light sources within the space where the light is used.*"

Hed, Column 2, lines 55 to 66:

> "*In a second aspect of the invention, light is transmitted from remotely positioned complementary light sources to a luminaire which contains light extraction elements ... The light extractor based luminaire can be used for ... the control and shifting of human circadian cycle ...*"

Hed, after discussing a device with light emitters in the housing, Column 3, lines 55 to 66:

> "*Alternatively, the luminaire can comprise: ... a multiplicity of elongated light guides in the housing ... The diffuser can form a wall of a space to be illuminated, for example, the wall of ... a treatment facility for modifying the circadian rhythm ...*"

Hed, Column 4, lines 46 to 48:

> "*FIG. 7 is a view ... of a human circadian adjusting system using light-extractor-based luminaire of the instant invention;*"

Hed, Column 13, line 32 to column 14, line 15:

> "*In FIG. 7 we show a typical system ... for the implementation of shifting and control of human circadian cycles. ... In implementing this technology, it is necessary to reject very large quantities of heat ... The light sources and the concentrators are located in a facility, or a shelter outside the room where the*

treatment is given, and thus problems associated with heat rejection into working or living habitats are circumvented."

Hed never suggests that all embodiments are suitable for modification and resetting of the human circadian cycle and never suggest any LED-based solution for devices for modification and resetting of the human circadian cycle. As such, the Examiner's statement "the intended use of the luminaire", which infers that resetting the circadian clock is disclosed as the use for all the luminaires in the application, is clearly incorrect. Also, it is clearly incorrect to allege that "no limitation regarding the various embodiments can be inferred".

Second, when countering Applicants' arguments, the Examiner also stated "the LED version within the housing (Figure 3), includes cooling means". The relevance of this statement is uncertain and nothing in respect of Figure 3 suggests an LED-based light therapy device. However, recall that in regards to all of the luminaires described to in Column 4, line 54 to Column 10, line 44, including Figure 3, Hed states at column 10, lines 45 to 62:

"*One of the shortcomings of the embodiments described above involves their application when very high levels of luminous flux are desired. Since light emitting diodes have an overall efficiency of converting electricity to light in the range of 8% to 12%, the balance of energy is dissipated as heat. When very high luminous output of 5000 lumens per square meter and higher are required, the heat generated at the luminaire may become too high for passive dissipation and can cause an appreciable rise in the temperature of the luminaire. ... in a number of environments, it is not advisable to have "live" electrical wiring connections in the illuminated zone.*

I can overcome these shortcomings by positioning the light source remotely from the luminaire and transmitting the light into the luminaire ..."

Thus, cooling means or not, the embodiment of Figure 3 is considered by Hed to have the same shortcomings as the luminaires of Figures 1, 2 and 4 and is thereby separated from any light treatment device taught by Hed.

In view of the foregoing, it is clear that the Hed reference does not teach or suggest a light treatment device with an LED light source. In fact, Hed teaches away from installing LEDs in a device for modification and resetting of the human circadian cycle.

The Examiner is reminded that combining prior art elements is not sufficient to render the claimed invention obvious if the results would not have been predictable to one of ordinary skill in the art because of a teaching away in the prior art (MPEP 2143, summarizing *United States v. Adams, 383 U.S. 39, 51-52, 148 USPQ 479, 483-84 (1966)*) and "When the prior art teaches away from combining certain known elements, discovery of successful means of combining them is more likely to be nonobvious." (*KSR International Co. v. Teleflex Inc., 550 U.S., 82 USPQ2d 1385, 1395-97 (2007)*).

Since Hed fails to teach or suggest a light treatment device with an LED light source and Reichborn-Kjennerud *et al.* adds nothing that would render the claimed invention obvious, the rejection of claims 1, 15 to 21 and 34 to 38 under 35 USC § 103 must be withdrawn.

Claim Rejections – 35 USC § 103 - Claims 2 to 13, 22 to 32, 39 to 49, 51 to 69, 136 to 141 and 143 and Claims 14, 33, 50, 70 to 71, 74-76, 78 to 80, 82 to 96, 98 to 109, 110 to 121, 123 to 130, 132 to 135 and 142

The Examiner rejected claims 2 to 13, 22 to 32, 39 to 49, 51 to 69, 136 to 141 and 143 of the application as being unpatentable over Hed in view of Reichborn-Kjennerud *et al.* and further in view of Brainard *et al.* (2001) Action Spectrum for Melatonin Regulation in Humans: Evidence for a Novel Circadian Photoreceptor. J Neurosci 21(16):6405-6412. The Examiner also rejected claims 14, 33, 50, 70 to 71, 74 to 76, 78 to 80, 82 to 96, 98 to 109, 110 to 121, 123 to 130, 132 to 135 and 142 as being unpatentable over Hed in view of Reichborn-Kjennerud *et al.*, Brainard *et al.* and one of Ellens *et al.* (US Patent no. 6,504,179) or Czeisler *et al.* (US Patent no. 5,167,228).

In these rejections, the Examiner admits that neither Hed nor Reichborn-Kjennerud *et al.* teach ocular light treatment using specific treatment wavelengths and alleges that Brainard *et al.* teach ocular light therapy using light in the range of 466 to 477 nm.

As set out previously, applicants do not agree that these claims are in any way rendered obvious by the cited references. As stated above, Hed does not teach or suggest a light treatment device with an LED light source and Brainard *et al.* add nothing to Hed to overcome this deficiency. Further, as stated in our response filed May 29, 2008:

- A person skilled in the relevant art would not apply the teachings of Brainard *et al.* to arrive at a device as presently claimed.

In support of this assertion, we had filed a Declaration under 37 CFR 1.132 to confirm the assessment of a person skilled in the art of ocular light therapy, Dr. Raymond Lam. In response to the Declaration, the Examiner countered that (i) "Dr. Lam has provided his opinion of his interpretation of the prior art with no substantiating data or scientific evidence."; and (ii) "the "Canadian Consensus Guidelines for the Treatment of Seasonal Effective Disorder, coauthored by Dr. Lam, indicates several different light sources with no clear preference for one over another for light therapy." Applicants have studied the Examiner's assertions and reviewed them with Dr. Lam. A second Declaration under 37 CFR 1.132 has been prepared and is enclosed to address the Examiner's allegations.

In the attached Declaration, Dr. Lam confirms that, in his opinion, the efficacy for one type of light is not automatically applicable to another type of light without study and explains the differences between the light used in the Brainard *et al.* reference cited by the Examiner and an LED light source. To address the Examiner's allegation that this opinion was not substantiated, Dr. Lam identifies and explains numerous scientific references that evidence and support, with respect to light therapy, that the efficacy for one type of light is not automatically applicable to another type of light.

Interestingly, in his Declaration Dr. Lam refers to a second paper by Brainard, included in Exhibit D (Brainard *et al.*, (1990) Effects of different wavelengths in seasonal affective disorder. J Affect Disord 20:209-216), wherein blue fluorescent light was used for a light therapy study. From that study, Brainard reported that the blue fluorescent source did not produce a phototherapeutic effect over placebo. Based on the foregoing, clearly it would not be obvious for the skilled person to apply the results from one type of light to

another type of light, whether the difference is with respect to the light source itself, the intensity of the light source or the mode of delivery of the light.

Further, with respect to the Examiner's allegation that Dr. Lam's publications do not indicate a preference of one light source over another for light therapy, this allegation is not true. Dr. Lam has declared that he regularly states his preferences for one type of light over another, as shown in his book, Clinical Guidelines for the Treatment of Seasonal Affective Disorder, included at Exhibit E of his Declaration.

As declared by Dr. Lam, a person skilled in the art would not apply teachings based on one type of light source, such as those of Brainard et al. (2001), to an LED-based device. As such, the rejections under § 103 based on the combination of Hed, Reichborn-Kjennerud *et al.* and Brainard *et al.* (2001) should be withdrawn.

It is submitted that although the Examiner alleges that further claimed elements are taught by various of the references or by common knowledge, we do not agree with at least some of these rejections. In any event, none of the additionally cited references add anything to Hed, Reichborn-Kjennerud *et al.* and Brainard *et al.* (2001) to overcome the significant deficiencies in the cited references already noted herein above.

Unspecified Claim Observations

Claims 99, 112, 114, 124, 126, 133 and 135 were identified by the Examiner as having no affect on the method in a manipulative sense and as being given no patentable weight. Since these claims depend from claims that are already clearly patentable, the Examiner's comments are simply noted at this time.

With respect to claims 98, 111, 123 and 132, without formulating any rejection to the claims, the Examiner alleges that the subject matter of these claims was not disclosed as critical. On the contrary, applicants consider the subject matter of these claims to be worthy of patent protection and have framed these claims with the intent of seeking patent protection for the defined features of the invention. The Examiner suggests that a skilled artisan would understand various effects, but the noted effects have nothing at all to do with the claimed subject matter. If the Examiner does not have the grounds to

properly reject these claims under the statutes or regulations, then these claims should be indicated as allowable.

Skepticism of Experts

As further evidence of nonobviousness, applicants refer to page 4 of the Declaration pursuant to 37 CFR § 1.132 by Dr. Lam. Dr. Lam, who is clearly an expert in the field of light therapy, states that although he originally did not believe that the presently claimed device would offer any therapeutic effect, a recent study, Desan *et al.* (2007) A controlled trial of the Litebook light-emitting diode (LED) light therapy device for treatment of Seasonal Affective Disorder (SAD). BMC Psychiatry 7:38, demonstrated to him that our claimed device is an effective light therapy device. Dr. Lam characterized these results as surprising. The skepticism of an expert, which is later overcome, is strong indicia of nonobviousness.

Commercial Success and Licensing

In further support of patentability, Applicant submits herewith a declaration by co-inventor Larry Pederson pursuant to 37 CFR § 1.132 attesting to the commercial success and licensing of the invention. As evident in the declaration, Applicant was the first to invent and commercialize a light therapy device that enjoyed commercial success due to features and advantages claimed in the present application and disclosed or inherent in the specification. The commercial success of Applicant's light therapy device, as well as the innovativeness of the device, was well recognized in the industry as evidenced by, inter alia, licenses to sell devices granted by Applicant. The commercial success and licensing of the invention is strong indicia of nonobviousness.

Conclusions

The rejections under 35 USC § 103 should be withdrawn based on one or more of:

- Hed fails to teach or suggest an ocular light therapy device including an LED light source and none of the secondary references add anything to Hed in this regard.

- As stated by way of Declaration, a skilled person would not apply the teachings of Brainard *et al.* (2001) to an LED-based device.

- Applicants have established by way of Declaration, that an expert in the area of ocular light therapy was, at about the time of filing the present application, skeptical with respect to the presently claimed invention, but that recently acquired data overcame that skepticism.

- Applicants have shown by way of Declaration, commercial success due to features and advantages claimed in the present application.

Applicants have addressed all of the rejections raised in the office action.

In view of the foregoing, applicants submit that the claims are in a condition for allowance.

Respectfully submitted,

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Date: Jan 9 | 09